jolife

K090422

JUN 17 2009

510(k) SUMMARY

Jolife's LUCAS 2

This document provides a brief summary of the LUCAS 2 device and its supporting information.

1) GENERAL DATA

510(k) submitter

Jolife AB
Ingmar Malm
Ideon
Scheelevägen 17
SE-223 70 Lund
Sweden

Phone: +46 46 286 50 00
Cell phone: +46 70 721 22 24
Fax: +46 46 286 50 10

e-mail: ingmar.malm@jolife.com

Contact person

Howard Holstein
Hogan & Hartson
Columbia Square
555 Thirteenth street NW
Washington DC 20004-1109

Phone: (202) 637-5813

Date when prepared

February 13, 2009

Trade name

LUCAS 2

Common name

Chest Compression System

Classification name

External cardiac compressor (21 CFR 870.5200)

Product code

DRM

Predicate devices

- Lucas 1 cleared under K062401
- Thumper model 1008 cleared under K073079
- Autopulse model 100 cleared under K072527

2) DESCRIPTION OF THE DEVICE

LUCAS 2 is an electrically powered mechanical chest compression system providing controlled automated chest compressions on adult patients who have acute circulatory arrest.

LUCAS 2 consists of an upper part containing the electrically driven piston rod, which acts on the patients chest via a pressure pad. The pressure pad is surrounded by a suction cup.

The support legs of the upper part are fastened to the back plate prior to starting compressions.

LUCAS 2 is designed to:

- Provide effective, consistent and uninterrupted compressions according to the guidelines given by American Heart Association (AHA);
- Provide good circulation during the patient transport process;
- Provide safety during transportation for both emergency medical personnel and patient, allowing emergency medical personnel to wear safety belts during transportation while LUCAS 2 delivers continuous, consistent and uninterrupted compressions;
- Provide hands-free compressions in any situation.
- Be applied to the patient with interruption of less than 20 seconds.

3) INTENDED USE / INDICATIONS FOR USE

LUCAS 2 Chest Compression System is to be used for performing external cardiac compressions on adult patients who have acute circulatory arrest defined as absence of spontaneous breathing and pulse, and loss of consciousness.

LUCAS 2 must only be used in cases where chest compressions are likely to help the patient.

4) COMPARISON TO PREDICATE DEVICES

The LUCAS 2 and its predicates have basically the same performance characteristics.

The LUCAS 2 has the same performance characteristics as the previuosly cleared LUCAS 1 device.

The LUCAS 2 and Thumper 1008 act on the chest via a pressure pad, while Autopulse acts on the chest via a circumferential belt.

The LUCAS 2 and Autopulse are battery powered, while the Thumper 1008 is powered by compressed oxygen while the previously cleared LUCAS 1 is powered by compressed air.

5) SUMMARY OF SUBSTANTIAL EQUIVALENCE

LUCAS 2 is substantially equivalent to the predicate devices. The LUCAS 2 has the same intended use and substantially similar indications for use, basic overall function, and performance as its predicate devices.

6) MATERIALS

All materials used in the manufacture of LUCAS 2 are suitable for its purpose and are well known and are the same as those materials and intended use as the materials included in the 510(k)-cleared LUCAS 1 (K062401).

7) TESTING

Appropriate product testing was conducted and included a number of function tests during different operating conditions. These tests demonstrated that the functionality, safety, efficacy and capability of LUCAS 2 comply with the product specifications and safety standards and support substantial equivalence to predicate devices.

In all instances, the LUCAS 2 functioned as intended and all results observed were as expected.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 31 2011

Jolife AB
c/o Mr. Howard M. Holstein
Hogan Lovells US LLP
Columbia Square
555 13th Street, NW
Washington, DC 20004

Re: K090422
LUCAS 2
Regulation Number: 21 CFR 870.5200
Regulation Name: External Cardiac Compressor
Regulatory Class: Class III
Product Code: DRM
Dated: May 18, 2009
Received: May 18, 2009

Dear Mr. Holstein:

This letter corrects our substantially equivalent letter of June 17, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. H. Hillebren

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

jolife

Indications for Use

510(k) Number (if known): K090422

Device Name: LUCAS 2

Indications for Use:

LUCAS Chest Compression System is to be used for performing external cardiac compressions on adult patients who have acute circulatory arrest defined as absence of spontaneous breathing and pulse, and loss of consciousness.

LUCAS must only be used in cases where chest compressions are likely to help the patient.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K090422

JOLIFE AB, Ideon Science Park, SE-223 70 Lund, Sweden. Visiting Address: Scheelevägen 17
Tel: +46 (0) 46 286 50 00, Fax: +46 (0) 46 286 50 10, E-mail: info@jolife.com, www. jolife.com